01/10/2011

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## NOTICE OF ALLOWANCE AND FEE(S) DUE

YOUNG & THOMPSON

209 Madison Street Suite 500 Alexandria, VA 22314 EXAMINER
SHAFER, SHULAMITH H
ART UNIT PAPER NUMBER

ART UNIT 1647 DATE MAILED: 01/10/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,995	07/25/2002	Marinus Gerardus Cornelis Kivits	2001-1028	5816

TITLE OF INVENTION: PROCESS FOR OBTAINING GROWTH FACTOR PREPARATION (TGF-BETA AND IGF-I) FROM MILK PRODUCTS HAVING LOW MUTUAL CROSS-CONTAMINATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0	\$1510	04/11/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless corrects maintenance fee notifica	correspondence includir ed below or directed oth	of transmitting the 1336 ig the Patent, advance of herwise in Block 1, by (a	rders and notification of r a) specifying a new corres	naintenance fees w pondence address;	ill be and/or	mailed to the current (b) indicating a sepa	correspondence address as arate "FEE ADDRESS" for
IMBITHERABLE FOR INCIDENCES OF THE STATE OF				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
466 YOUNG & TF 209 Madison Str Suite 500	reet	/2011	I bo	Cer	tificate	of Mailing or Trans	mission g deposited with the United st class mail in an envelope above, or being facsimile ate indicated below.
Alexandria, VA	22314						(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
10/089,995 TITLE OF INVENTION HAVING LOW MUTUA		TAINING GROWTH FA	rinus Gerardus Cornelis K CTOR PREPARATION		IGF-	2001-1028 I) FROM MILK PR	5816 ODUCTS
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE	TOTAL FEE(8) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0		\$1510	04/11/2011
EXAM	IINER	ART UNIT	CLASS-SUBCLASS				
SHAFER, SH	ULAMITH H	I647	424-157100				
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required.  3. ASSIGNEE NAME A	ND RESIDENCE DATA less an assignee is ident h in 37 CFR 3.11. Comp	"Indication form and. Use of a Customer A TO BE PRINTED ON	(I) the names of up to or agents OR, alternative (2) the name of a single registered attorney or a 2 registered patent atto listed, no name will be THE PATENT (print or type data will appear on the p T a substitute for filing an (B) RESIDENCE: (CITY	vely, e firm (having as a gent) and the name meys or agents. If printed. ec) atent. If an assigna assignment.	memb es of u no nam	er a 2p to p to se is 3	ocument has been filed for
Please check the appropr	iate assignee category or	categories (will not be pr	inted on the patent):	Individual 🗖 Co	rporati	on or other private gr	oup entity Government
4a. The following fee(s)  Issue Fee Publication Fee (N	vo small entity discount p		b. Payment of Fee(s): (Plea A check is enclosed. Payment by credit car The Director is hereby overpayment, to Depo	d. Form PTO-2038	is atta	ched.	shown above)  ficiency, or credit any n extra copy of this form).
- 11	s SMALL ENTITY state	is. See 37 CFR 1.27.	b. Applicant is no lon				
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than t Office.	he applicant; a regi	stered a	attorney or agent; or the	ne assignee or other party in
Authorized Signature				Date			
Typed or printed name				Registration N	o		
This collection of inform an application. Confiden submitting the complete this form and/or suggests Box 1450, Alexandria, V Alexandria, Virginia 223	nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC k13-1450.	FR 1.311. The informatis U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to th O NOT SEND FEES OR	on is required to obtain or r 1.14. This collection is est depending upon the indiv e Chief Information Office COMPLETED FORMS TO	etain a benefit by the imated to take 12 re idual case. Any co rr, U.S. Patent and D'THIS ADDRESS	ne publ ninutes mment Traden . SENI	tic which is to file (and to complete, including the amount of times of the complete, U.S. Dep D TO: Commissioner	d by the USPTO to process) ng gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450,

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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



# UNITED STATES PATENT AND TRADEMARK OFFICE

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466	7590	01/10/2011		EXAMINER		
YOUNG & THOMPSON			SHAFER, SHULAMITH H			
209 Madison St	reet			ART UNIT	PAPER NUMBER	
Suite 500 Alexandria, VA	22214			1647		

# Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 1228 day(s). Any patent to issue from the above-identified application will include an indication of the 1228 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Application No. Applicant(s) 10/089 995 KIVITS ET AL. Notice of Allowability Examiner Art Unit SHIII AMITH H SHAFER 1647 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTQL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 8/16/07 and BPAI decision of 10/12/10. The allowed claim(s) is/are 16-23,33-35, now renumbered1-11. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) $\square$ All b) ☐ Some\* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \* Certified copies not received: \_\_\_\_\_. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

U.S. Patent and Trademark Office	
PTOL-37 (Rev. 08-06)	

/Shulamith H. Shafer/ Primary Examiner, Art Unit 1647

Attachment(s)

1. | Notice of References Cited (PTO-892)

Paper No./Mail Date

of Biological Material

2. Notice of Draftperson's Patent Drawing Review (PTO-948)

4. T Examiner's Comment Regarding Requirement for Deposit

Information Disclosure Statements (PTO/SB/08).

9. ☐ Other

5. Notice of Informal Patent Application

 Interview Summary (PTO-413), Paper No./Mail Date .

7. X Examiner's Amendment/Comment

8. T Examiner's Statement of Reasons for Allowance

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Art Unit: 1647

### EXAMINER'S COMMENTS

Claims 16-23 and 33-35 are allowable.

The application is allowable for the reasons set forth on page 7 of the decision of the Board of Patent Appeals and Interferences of 12 October 2010.

The closest prior art teaches the following:

Belford et al. (1997, J of Endocrinology 154:45-55) discloses isolation of a fraction rich in growth factors, including TGF-β and IGF-1, from whey by single step cation exchange chromatography;

Kussendrager et al. (1998 EP 0869134) teaches a process for recovering one or more growth factors from milk or milk derivatives comprising adsorbing the starting product to a cation exchanger, followed by fractionated elution of the cation exchanger.

Quinque et al. (1992, WO 9200014) teach a two step method to isolate growth factors from colostrums, the method comprising contacting the colostrums with a cation exchanger and subjecting the fraction obtained by elution of the cation exchanger to hydroxyapatite adsorption. The fraction retained on the hydroxyapatite is recovered by elution with phosphate buffer. The retained, active fraction contains growth factors.

None of these teachings, either individually or combined, anticipate the methods of the claimed invention: a two step process to obtain the following fractions:

a fraction comprising IGF-1, wherein the ratio IGF-1 to TGF- $\!\beta$  is greater than 10:1

a fraction comprising TGF- $\beta$ , wherein the ratio TGF- $\beta$  to IGF-1 is greater than 5:1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee.

Application/Control Number: 10/089,995

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shulamith H. Shafer/ Primary Examiner, Art Unit 1647